K061439 (pg 1 of 2)

TORNIER

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Summary of Safety and Effectiveness information
Special 510(k) Premarket Notification – Aequalis Reversed Shoulder Prosthesis

Regulatory authority: Safe Medical Devices Act of 1990, 21 CRF 807.92

1) Device name

Trade name:	*AEQUALIS Reversed Shoulder Prosthesis*
Common name:	Total-Shoulder System and Hemi-Shoulder System
Classification name:	Shoulder joint metal/polymer semi-constrained cemented prosthesis

2) Submitter

Tornier
Rue Doyen Gosse
38330 Saint Ismier - France

3) Company contact

Tornier
Mrs Mireille Lémery
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161, rue Lavoisier - Montbonnot
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4) Classification

Device class:	Class II
Classification panel:	Orthopedic
Product code:	KWS

5) Equivalent / Predicate device

Aequalis Reversed Shoulder Prosthesis, TORNIER SA, K030941, K041873, K050316
Aequalis Shoulder System, TORNIER SA, K952928, K012212, K041339, K060209
Delta Shoulder, DePuy Inc, K021478

6) Device description

The *Aequalis Reversed Shoulder Prosthesis* is intended to be used to relieve pain and significant disability following massive and non repairable cuff-tear associated to arthropathy and following massive cuff-tear arthropathy. In this case, the rotator muscles of the shoulder (supraspinatus, infraspinatus, teres minor and long head of the biceps) are no more useful for mobility, and only the deltoid (for abduction and external rotation) and the subscapularis (for internal rotation) are functional.
Therefore, the usual goal of such surgery is to restore the shoulder joint to facilitate its working condition and to reduce or eliminate pain. The *Aequalis Reversed Shoulder Prosthesis* is intended to accomplish these

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S.A.S. au capital de 288 000 €
SIRET : 070 501 275 000 13
R.C.S. : 070 501 275
CODE APE : 331 B

SIEGE SOCIAL : rue du Doyen Gosse - 38330 SAINT-ISMIER - FRANCE

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goals. Its reversed design allows to medialize the center of rotation of the shoulder, lengthening the deltoid muscle lever arm.
The *Aequalis Reversed Shoulder Prosthesis* is a semi-constrained system composed of a humeral and a glenoid parts.

The present device modification submission consists in some additions and changes for metaphyseal screw, glenoid baseplate, glenoid sphere and insert.

7) Materials

Metaphyseal inserts are made of ultra high molecular weight polyethylene (UHMWPE). The base of the glenoid implant is manufactured from Titanium alloy. The sphere is manufactured from Cobalt-Chromium alloy and the screw is manufactured from Titanium alloy.
The hydroxylapatite coating conforms to the ASTM standard F 1185. The coating is performed by BioCoat, Inc. according to their Master File MAF-339.

8) Indications

The Aequalis Reversed Shoulder Prosthesis is indicated for patients with a functional deltoid muscle as a total shoulder replacement for the relief of pain and significant disability following arthropathy associated to massive and non repairable rotator cuff-tear. This device is also indicated for the prosthetic revisions with massive and non repairable rotator cuff-tear. Only the humeral components are for cemented use. The glenoid implant is anchored to the bone with 4 screws and is for non-cemented fixation.
When during the primary surgery the glenoid bone stock appears to be insufficient to bear the reversed glenoid components or when glenoid bone fracture occurs during the surgical procedures, the hemi-prosthesis adaptor and the union screw can be adapted to the humeral components in order to transform the Aequalis Reversed prosthesis into a non reversed hemi-prosthesis.
When, in case of revision of a Aequalis Reversed prosthesis, the glenoid bone stock appears to be insufficient to implant a base plate and a sphere of Aequalis Reversed range again, the use of the hemi-prosthesis adaptor and the union screw allows for the transformation of the Aequalis Reversed prosthesis into a non reversed hemi-prosthesis in order to avoid the revision of the humeral components.

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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
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Rockville MD 20850

JUL 20 2006

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% Mireille Lemery
Regulatory Affairs Manager
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Re: K061439
Trade/Device Name: Aequalis Reversed Shoulder Prosthesis
Regulation Number: 21 CFR 888.3660
Regulation Name: Shoulder joint metal/polymer semi-constrained cemented prosthesis
Regulatory Class: Class II
Product Code: KWS
Dated: June 30, 2006
Received: July 3, 2006

Dear Ms. Lemery:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.
This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at 240-276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Mark N. Melkerson
Director
Division of Generative, Restorative
And Neurological Devices
Center for Devices and
Radiological Health

Enclosure

Indications for Use

K061439

510(k) Number (if known):

Device Name: *Aequalis Reversed Shoulder Prosthesis*

Indications For Use:

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Prescription Use X (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Barbara Bueltmann

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices